REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application. Claims 1-2 and 5-7 are currently pending in this application. Claim 1 has been withdrawn from further consideration. Claims 3-4 have been cancelled. No new matter has been added by way of the present amendment. The amendment to claim 2 is supported by the Specification at, for example, page 9, lines 14-21, as well as Examples 1 and 2. New claims 3-5 are supported by the Specification at, for example, page 7, lines 10-12 and page 10, lines 24-26. Accordingly, no new matter has been added.

In view of the amendments and remarks herein, Applicant respectfully requests that the Examiner withdraws all outstanding rejections and allow the currently pending claims.

Issues Under 35 U.S.C. § 103(a)

Claims 2-4 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoshida (U.S. 2003/0232450) (hereinafter Yoshisda '450) in view of Takanori et al. (JP 2002-086399) (hereinafter Takanori '399). Applicant respectfully traverses.

The Examiner asserts that Yoshida '450 discloses a method for manufacturing a microfluidic device comprising the steps of: forming a resin layer (2) on a substrate (1), forming a groove or channel (5) by removing a portion of the resin layer by laser processing and forming a "throughhole" or inlet via laser processing. The Examiner acknowledges that Yoshida '450 does not teach or suggest the formation of subsequent resin layers to form a three-dimensional fluidic circuit, and relies on the teachings of Takanori '399 to overcome this deficiency.

Applicant initially notes that claims 3-4 have been cancelled by way of the present amendment. Accordingly, the rejection of these claims is moot.

As to claim 2, Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, there must be a reason why one of ordinary skill in the art would modify the reference or combine reference teachings to obtain the invention. A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the "teaching, suggestion, motivation test" is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.*

The State of the Art and Technical Significance of the Present Invention

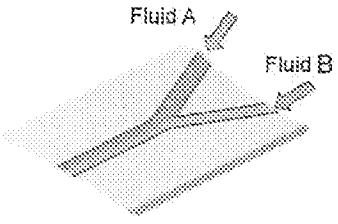
In recent years, development of a micro total analysis system (μ-TAS) has advanced, including applications of μ-TAS to genetic diagnosis, poison inspection and the like. Particularly, if this technology is established in medical fields, high-accurate biochemical analysis can be sanitarily performed. Further, μ-TAS have been used in an attempt to provide

customized medical treatments by finding the causes of intractable diseases (see page 1, line 10 to page 2, line 20 of the present specification).

However, up until the present time, μ-TAS has not been successfully reduced to practice. The fluid flow path of the devices is micro-fine. If the devices are manufactured by means of impractical steps such as photolithography, which lacks design freedom (see Takanori '399), the manufacturing time and costs are so excessive so as to be unsuitable for practical enlargement in applicable fields.

In view of the above, alternatives have been proposed, such as a fluidic device, a part of which can be recycled (see Yoshida '450). However, this device has a two-dimensional (plane) fluid flow path. When a plurality of fluids are joined, respective fluids flow in parallel as shown in FIG. A below, and sufficient mixing of the fluids is not accomplished. Therefore, mixing must be forced by providing an electrode in the fluidic device, which reduces the cost-effectiveness of the device. In addition, in order to perform the above-described electrical mixing, the fluid is limited to fluids in which electric migration occurs, and thus, the scope in which the device can be applied is remarkably limited (see page 3, line 14 to page 4, line 3 of the present specification).

[FIG. A]



The present invention aims to solve the above-described problems. Thus, the objects of the present invention include (i) achieving a three-dimensional micro-fine fluid flow path capable of performing rapid mixing of fluids, (ii) manufacturing efficiency and cost-effectiveness, and (iii) possibility to recycle the substrate. The present inventor has accomplished the above-described objects and provides a practical method of manufacturing a micro fluidic device suitable for μ-TAS (see page 15, lines 16 to 20 of the present specification). Thereby, the present inventor has reduced to practice a method applicable to new genetic diagnosis and biochemical analysis procedures, in a wide range of technology areas and medical fields, thus greatly contributing to public health.

Technical Features of the Present Invention

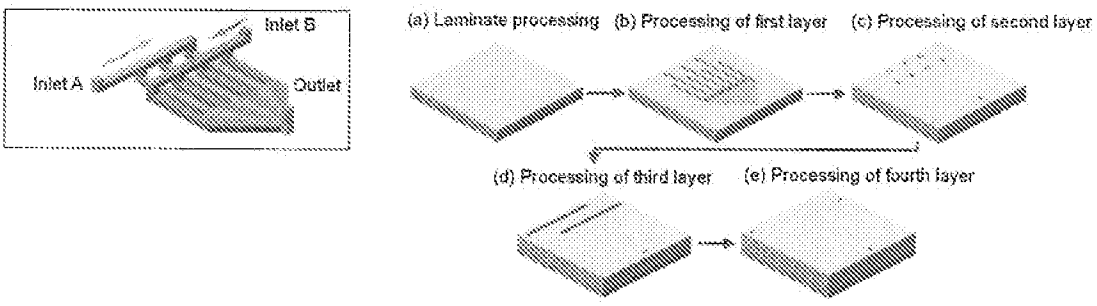
(a) Lamination of resin film layers

The present invention employs a step of stacking on a substrate resin films formed by a lamination method (see page 9, line 8 to page 10, line 1 of the present specification). This step is different from the step of processing using a coated film of a fluid resin (Takanori '399) and provides a film layer on a substrate which does not flow out of the resin because of its stable form. Thereby, handling and processing are largely improved by the method of the present invention.

(b) Formation of micro-fine fluid flow path by laser processing

The present invention employs a step of forming a fluid flow path by laser processing which utilizes a laser ablation phenomenon (see page 8, line 17 to page 9, line 7 of the present specification). Therefore, by arbitrarily moving a laser irradiating position, it is possible to form a fluid flow path in a desired shape without substantial limitation. For example, even complicated micro-fine three-dimensional fluid flow paths, as shown in FIG. B below (FIG. 1 and FIG. 2 of the present specification) can be manufactured by forming a groove and a hole in a desired form while each layer is precisely controlled. Accordingly, even when the structure of a fluid flow path is frequently changed in order to provide customized medical treatment to individual patients, the device of the present invention can effectively meet particular needs without cost increases.

[FIG. B]



(c) Lack of unnecessary materials and processing steps

According to the manufacturing method of the present invention, all fluid flow paths from an inlet to an outlet, as shown in FIG. B above, are formed in laminated resin films. Accordingly, the above-described laser processing method is used to form micro-fine fluid flow

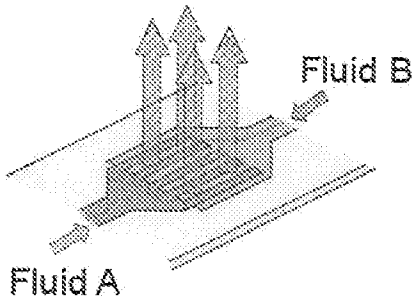
paths in all film layers. The device of the present invention does not require unnecessary steps and materials such as a pipe and a temporary substrate (Takanori '399), and high manufacturing efficiency and cost-effectiveness are accomplished.

Advantages of the Present Invention

(a) Manufacturing three-dimensional structure of micro-fine fluid path

According to the manufacturing method of the present invention, it is possible to form three-dimensional micro-fine fluid flow paths having a branch portion and a merge portion. This results in three-dimensional fluid mixing, as shown in FIG. C below (see FIG. 7 of the present specification), which could not be performed in the conventional two-dimensional fluid flow path. Thus, a plurality of fluids can be mixed rapidly and uniformly. Further, regarding the mixing of reactive fluids, the present invention can largely accelerate its reaction speed in comparison with conventional electrical mixing (see page 10, lines 6 to 20 of the present specification).

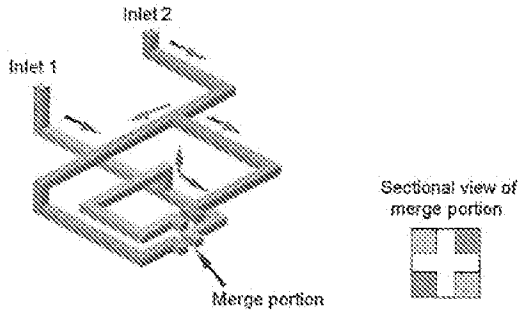
[FIG. C]



(b) Accurate micro-fine fluid path formation by which a complicated fluid flow path structure can be formed

According to the manufacturing method of the present invention, it is possible to form three-dimensional fluid flow paths of micrometer order under micro-fine and precise control even if a fluid flow path structure has a complicated branch portion and a complicated merge portion. It is also possible to form a fluid flow path structure having a micro-fine fluid flow path (in the order of several ten μm) and a remarkably intricate path shape, as shown in FIG. D below, with accurate processing (see FIG. 5 of the present specification).

[FIG. D]



(c) Formation of micro-fine fluid flow path with high efficiency and cost-effectiveness

According to the manufacturing method of the present invention, it is possible to three-dimensionally manufacture a micro-fine fluid flow path showing an excellent function as described above, even if a fluid flow path structure has a complicated branched portion and a complicated merge portion, with efficiency and cost-effectiveness (low cost) (see page 8, line 3 to page 9, line 7 of the present specification). The present invention provides the first practical

method of manufacturing a micro fluidic device which is suitable for μ-TAS and which can be manufactured on an industrial scale.

(d) Possibility of recycling the substrate

Because a micro fluidic device manufactured according to the manufacturing method of the present invention has a fluid flow path provided in a resin film, it is possible to recycle the substrate portion of the device by washing out the portion of the resin film and not throwing away the substrate portion (see page 11, lines 24 to 25 of the present specification). For example, a luminous detection device in a genetic diagnosis system or the like employs a quartz substrate with remarkably high transparency. It is possible to recycle such expensive substrate with high quality to largely reduce costs, thereby contributing to the advancement of a leading biochemistry technology.

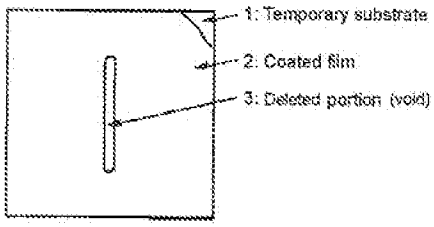
Distinctions Over the Prior Art of Record

Takanori '399

(a) Takanori '399 requires processing by photolithography

The manufacturing method of a microdevice according to Takanori '399 essentially requires 1) a step of coating a fluid resin on a temporary substrate to form a coated film, 2) a step of fitting a photomask to the coated film, 3) a step of photo-curing a part of the coated film by irradiating the part with an ultraviolet ray through the photomask, and 4) a step of washing out an uncured part of the coated film. Thereby, a coated film (2) having a deleted portion or (void) (3) on the temporary substrate (1) is formed, as shown in Fig. E below (see Fig. 1 of Takanori '399, and paragraphs [0185]-[0187]).

[FIG. E]



The above photomask itself requires micro-fine processing accuracy, and thus, the manufacturing process is long and costly. In addition, because different photomasks must be prepared corresponding to changes in design of a fluid flow path, this largely increases the manufacturing cost of a fluidic device. Photolithography is complicated in and of itself, as described above, and Takanori '399 further employs a step of transferring a coated film (as described below), which requires an even more complicated procedure. Therefore, it is practically impossible for Takanori '399 to provide branched fluid flow paths and a merge portion of the paths having an intricate shape.

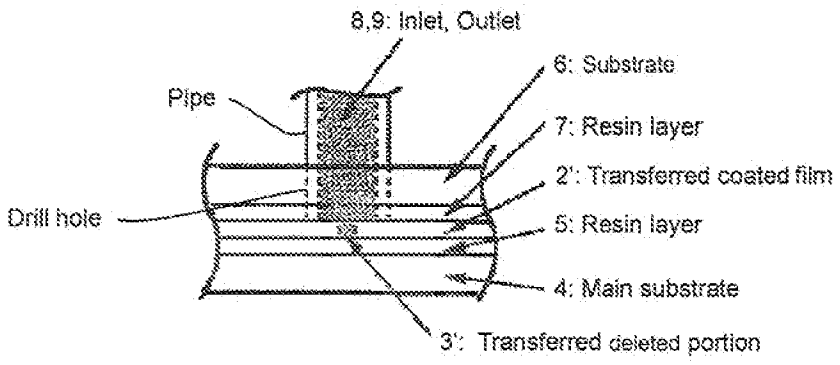
In stark contrast, the present invention employs laser processing with high design freedom and cost-effectiveness. Therefore, it is possible to manufacture a micro-fine, three-dimensional fluid flow path.

(b) Takanori '399 requires a step of transferring a coated film with a temporary substrate

In Takanori '399, in order to keep and fix the shape of the deleted portion (3) of the coated film (2) formed on the temporary substrate, the coated film is transferred to the resin layer (5) on the main substrate (4) prepared separately (see FIG. F below, as well as Fig. 3 in Takanori '399). Thereafter, the temporary substrate (1) is removed. Next, a substrate (6) (different from main substrate (4)) having a resin layer (7) formed thereon is prepared, and the substrate (6) is

bonded onto the transferred coated film (2') so that the resin layer (7) faces the transferred coated film (2') (see paragraphs [0188] to [0192] of Takanori '399).

[FIG. F]



In stark contrast, the present invention does not require a step of transferring a coated film with a temporary substrate.

(c) Differences in action and effects

(i) The processing procedure of Takanori '399, employing photolithography and resin transfer, cannot provide an inlet and an outlet. Further, it requires a step of opening a hole with a drill and inserting a pipe into it. In such a processing method, a micro-fine fluid flow path cannot be provided, and finally large holes with a diameter of 1.6 mm are provided as an inlet and an outlet fluid flow path (see paragraph [0194] of Takanori '399).

In contrast, the present invention permits the formation of micro-fine fluid flow paths, including an inlet and an outlet, in the order of several ten μm.

(ii) Takanori '399 provides a micro device in which a deleted portion likely to be damaged is shaped to form a cavity. In Takanori '399, the deleted portion is in an unstable cured state, due to light irradiation. Thus, the objective of Takanori '399 is to transfer a coated film so

as to keep its form and maintain form stability. That is, Takanori '399 is merely directed to a specific task (action and effect) in photolithography.

In contrast, the present invention does not utilize photolithography or the like. Rather, it employs laser processing of laminated films. Thereby, if a micro-fine, three-dimensional fluid flow path has a remarkably complicated shape, as well as a branch portion and a merge portion, the present invention can accomplish a significant improvement in producing a three-dimensional fluid flow path in stable form without using unnecessary steps and members. Further, the present invention allows for the recycling of a substrate if necessary.

(d) Conclusion

Clearly, Takanori '399 fails to teach or suggest every limitation of the present invention. Furthermore, one skilled in the art would not have been motivated to modify the teachings of Takanori '399 in an attempt to arrive at the present invention.

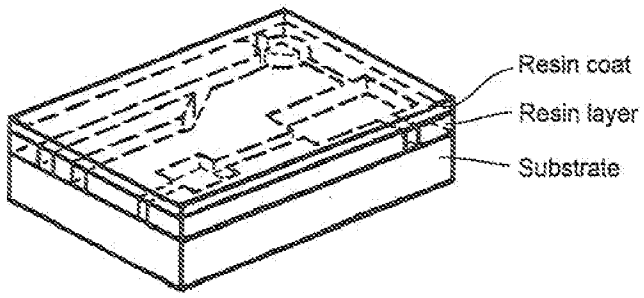
Yoshida '450

(a) Yoshida '450 requires a plane fluid flow path

Yoshida '450 essentially requires a plane fluid flow path, as shown in FIG. G below.

In contrast, the micro fluidic device obtained by the manufacturing method of the present invention has a three-dimensional fluid flow path having a branch portion and a merge portion three-dimensionally arranged therein. Clearly, the present invention is substantially different from Yoshida '450.

[FIG. G]



(b) Differences in action and effects

(i) According to the manufacturing method of the present invention, it is possible to three-dimensionally form a micro-fine fluid flow path. As a processing technology, two-dimensional processing of a structure is substantially different from three-dimensional processing of a structure. Yoshida '450 does not teach or suggest three-dimensional processing of a structure. In addition, the fluid flow path structure obtained by the present invention is micro-fine, in the order of micrometers. The practical technology capable of accurately forming a three-dimensional structure in a micro-fine space had not been developed prior to the present invention, as this technology has been developed by the present inventors for the first time.

(ii) By accomplishing a three-dimensional fluid flow path structure, as described above, it is possible to perform rapid mixing of fluids, even those difficult to mix, thereby largely accelerating the reaction speed of reactive fluids. Chemical luminescence by an electrochemical reaction or the like is utilized in a luminous detection device for genetic diagnosis and cell diagnosis (see page 9, lines 7 to 21 of the present specification), where rapidly mixing predetermined fluids to allow the reaction of the fluids to progress is critical.

(c) Conclusion

Clearly, Yoshida '450 fails to teach or suggest every limitation of the present invention. Furthermore, one skilled in the art would not have been motivated to modify the teachings of Yoshida '450 in an attempt to arrive at the present invention.

Combined teachings of Yoshida '450 and Takanori '399

As discussed above, the cited references, alone or in combination, fail to teach or suggest every limitation of the instant invention. For this reason alone, this rejection should be withdrawn.

Furthermore, assuming *arguendo* that Takanori '399 cured the deficiencies of Yoshida '450, it is noted that references cannot be arbitrarily combined. There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Courts have clearly established that, even when a combination of references teaches every element of a claimed invention, a rejection based on a *prima facie* case of obviousness is improper absent a motivation to combine. *In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

Takanori '399 utilizes photolithography as an essential technology. It is technically contradictory to apply the lamination method disclosed by Takanori '399 to Yoshida '450. That is, as described above, photolithography requires an essential process of coating a fluid resin and solidifying a part of the resin. In contrast, lamination of films is technically contradictory to photolithography in principle. Accordingly, one skilled in the art would not be motivated to

combine Yoshida '450 and Takanori '399. Further, even if Yoshida '450 and Takanori '399 were combined, one skilled in the art would not arrive at the present invention.

As noted previously, the present inventor has developed a novel process to three-dimensionally manufacture a complicated fluid flow path with higher accuracy than conventional manufacturing methods. The present method is also simpler and more cost-effective.

As discussed in detail above, the present invention accomplishes (i) formation of three-dimensional micro-fine fluid flow path capable of performing rapid mixing and reaction of fluids, (ii) increase in efficiency and cost-effectivness of the manufacturing process, and (iii) recycling of the device substrate. Accomplishment of those remarkably advantageous properties is neither disclosed nor suggested by the cited references. These results have never been accomplished before, thus evidencing the superior results obtained by the method of the present invention.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and objections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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